

Preliminary Amendment
Inventor: von Dyck et al.
Attorney Docket No.: 713072.28

REMARKS

Accompanying this Preliminary Amendment are a Utility Patent Application Transmittal (in duplicate); Fee Transmittal (in duplicate); a utility patent application (copy of the parent application as filed); copy of the Declaration filed in the parent application, a copy of the document of Assignment filed in the parent application, 17 sheets of drawings filed in the original application, five sheets of new drawings (Figures 28 – 35), Letter to USPTO Drafting Division; and Information Disclosure Statement. References listed were provided in the parent case and therefore are not resent. The filing fee is also enclosed. A newly signed Declaration, Power of Attorney; statement under 3.73(b), and new document of assignment will be filed after receipt of the Notice to File Missing Parts.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned “VERSION WITH MARKINGS TO SHOW CHANGES MADE”.

It is now believed that all of the pending claims in the present application, namely, claims 38 through 69 contain limitations and restrictions that patentably distinguish them over the known art. None of the known references, either alone or in any combination thereof disclose or suggest all of the novel features associated with the present pad for use with continent ostomy port as explained above, nor do the referenced constructions provide the specific advantages and objectives obtained by the present device. Favorable action and allowance of the claims is therefore respectfully requested.

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If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding this amendment, it is respectfully requested that Examiner please telephone Applicants' undersigned attorney in this regard.

In view of the foregoing, it is submitted that the claims define patentably over the prior art and that the specification and claims comply in all respects with the requirements. Accordingly, a notice of allowance is hereby solicited.

If Examiner intends to take any action other than allowance, or if any issue could be readily resolved or other action could be taken to advance this application, such as Examiner's amendment, it is requested that Examiner please telephone the undersigned.

Respectfully submitted,

Date:

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APPENDIX

INTERLINEATED MARKUP REFLECTING AMENDMENT

IN THE SPECIFICATION

Page 1, paragraph 1:

PAD FOR USE WITH CONTINENT OSTOMY PORT

Page 1, insert after the title:

--Related Applications:

This application is a Continuation-In-Part application which claims the benefit of pending U.S. Patent Application Serial No. 09/420,643, filed on October 19, 1999, which is a Divisional of and which claims the benefit of U.S. Patent Application Serial No. 09/030,685, filed February 25, 1998, issued March 7, 2000 as U.S. Patent No. 6,033,390.--

Page 6, between paragraphs 3 and 4 insert the following:

-- The invention is further, briefly, a pad for use with a continent ostomy port includes a body portion defining an aperture appropriately sized to place around the catheter of a continent ostomy port. The body portion of the pad is sized and shaped for placement against a user's skin beneath a face plate of the ostomy port. The pad is formed of a soft, flexible material to thereby cushion and protect a user's skin from contact with the ostomy port face plate, wherein the pad body portion has a distal surface which is domed and provided with a central indented region to thereby accommodate the distal portions of the continent ostomy port.--

Page 9, between paragraph 3 and 4, insert the following paragraphs: --

Fig. 28 is a schematic top plan view of a moisture barrier shim constructed in accordance with the invention.

Fig. 29 is a sectional view taken on line 29 – 29 of Fig. 28.

Fig. 30 is a sectional view taken on line 30 – 30 of Fig. 28.

Fig. 31 is a schematic upper perspective view of another embodiment of a moisture barrier/pad constructed in accordance with the present invention.

Fig. 32 is the same view as Fig. 31, but with a COP shown in place, to illustrate use of the pad.

Fig. 33 is a side elevational view of the pad of Fig. 31.

Fig. 34 is a bottom perspective view of the pad of Fig. 31.

Fig. 35 is a top plan view of the pad of Fig. 31.

Page 30, before the first full paragraph, insert:--

With reference to Figs. 28 through 35, there is disclosed another embodiment of the moisture barrier previously discussed herein with reference to Fig. 4. Figs. 28 – 30 illustrate a “shim”, generally designated 157, which is optionally used with a moisture barrier/pad 158 described hereafter. Shim 157 is substantially flat and in the preferred embodiment shown has a generally oval-shaped perimeter 157a, as illustrated in Fig. 28. Perimeter 157a is shaped to match the perimeter of pad 158. Thus, if the shape of the pad is something other than oval, if desired, the exterior perimeter of shim 157 can be altered accordingly. The overall size of shim

157 can vary, as desired, to either match the size of moisture barrier/pad 158, so as to act as a riser for the COP face plate, or the shim may be sufficiently smaller in exterior dimension to permit it to be seated within the underside (proximally) of COP 200 for enhanced absorption of stomal fluids.

The sectional views shown in Figs. 29 and 30 illustrate an example of useful dimensions (in inches) for shim 157, but it is foreseen that other dimensions will suffice, depending upon the particular circumstances of use, including stoma size and COP dimensions.

Shim 157 has a preferably circular interior side wall, which defines a through-hole 157b to surround the stoma. The size and shape of the throughhole can be varied as may be necessary to accommodate any variations in size and shape stomas of various individual users. The arrow indicated by "X" in Fig. 29 illustrates one useful surface site on shim 157 for optional application of an adhesive, such as a pressure sensitive adhesive and/or web adhesive, for example.

Figs. 31 – 35 illustrate an alternative embodiment, generally designated 158, of the new moisture barrier /pad. Inconsistencies in size between the figures may exist due to copying anomalies. In the preferred version shown, pad 158 is formed of molded foam material and has a low profile, as seen if Fig. 33, with a generally oval perimeter 158a (Fig. 35), although other perimeter designs can be useful. The pad body 159 has an outer (distal) surface 159a that is slightly domed, but formed in the central portion thereof with an indented region that accommodates the distal portions of a COP, such as that generally designated as 200 in Fig. 32.

In this embodiment, upper surface 159a is formed with a central depressed area that is generally cross-shaped, extends down into the body 159 and has a substantially flat floor 163. Floor 163 defines a central aperture 160 with a side wall 161, which is shown circular, but can be other shapes, if desired, to accommodate the shape of a catheter, such as that indicated at 214 in Fig. 32.

Floor 163 of pad 158 extends away from aperture 160 in two opposed channels 165, each having opposed, angled side walls 167, as seen most clearly in Figs. 31, 32 and 33. Channels 165 offer easy finger access to an optional grip 242 on a cap 228 of a COP.

Floor 163 extends at approximate right angles to channels 165 from aperture 160 in two opposed cut-out areas 169 bounded by arcuate walls 171 disposed radially outwardly from the center of pad 158. Floor 163 between cut-out areas 169 may be in the same plane as floor 163 between channels 165, if desired, or slightly stepped down, as is preferred and as is shown in Fig. 31. Cut-out areas 169 provide spaces in pad 158 to accommodate the COP 200 features, such as a bolster inflation port, as indicated at 252, or an access port for an ARV, as indicated at 254 in Fig. 32.

Fig. 34 shows that the lower (proximal) surface of pad 158 is preferably, although not necessarily, provided with a depending ring 158b. Ring 158b is disposed coaxially with opening 160, but spaced radially outward from opening 160 by a sufficient distance that ring 158b can be positioned outwardly of the stoma when pad 158 is in normal use position. Ring 158b preferably extends transverse to pad body 159, and slightly past the proximal extent of body 159, as

illustrated in Fig. 33. Alternatively, ring 158b can be omitted altogether, or can be shorter than the depth of the perimeter of pad 158. When ring 158b is present, a preferably continuous channel 158c is formed between ring 158b and perimeter 158a of pad 158. Channel 158c is optionally sized and shaped to correspond to and to receive shim 157, so that shim 157 is disposed in normal use between the bottom of pad 158 and the user's skin. Shim 157 can also be nested in the underside of pad 158 without the presence of ring 158b. This arrangement is especially useful if the shim is to provide wicking properties. Alternatively, as previously discussed, the shim can have exterior dimensions which correspond to the exterior perimeter dimensions of pad 158, or which even extend slightly beyond the perimeter of the pad.--

Page 40, paragraph 1:

[A continent ostomy port device has a generally planar face plate defining a selectively sealable aperture, which is alignable with the opening of a stoma formed in the body of a user of the device. A closure portion is connected to the generally planar face plate adjacent to the aperture and is adapted to permit selective and repeatable covering and uncovering of the aperture in the generally planar face plate. A catheter portion extends from one side of the face plate and extends proximally, and one end of the catheter portion is disposed interior of the user's body, within the ostomy site, when the port device is in normal use position. The catheter portion has continuous and generally cylindrical exterior and interior side walls, the latter defining a major lumen. The catheter portion is sized and shaped appropriately for non-surgical insertion through a stoma to a sufficient distance that the presence of the catheter portion within

the stoma provides a physical barrier which reduces the incidence of stoma prolapse, without the use of extraneous, externally applied materials or additional surgery. A removable cartridge is sized and shaped to fit snugly and slideably within the major lumen of the catheter portion of the device so as to be liquid-tight and to thereby prevent inadvertent escape of body waste material from the stoma through the device when the cartridge is in place, so that the user is not required to wear an ostomy bag, and to further thereby clean the interior side wall of the catheter portion as the cartridge is pressed into the major lumen of the catheter. A selectively operable anti-reflux valve that is attached internally of the proximal end of the catheter portion and is activated when it is desired to prevent escape of body waste through the port device, and deactivated when it is desired to permit passage of fluid through the port device. Retaining structure is connected to the catheter, and is non-surgically, snugly fittable into the stoma, to cause the port device to be self-retaining in a normal use position within a stoma of the user, without the need for special surgery and extraneous, external fixation materials such as tape, belts, and adhesives.] A pad for use with a continent ostomy port includes a body portion defining an aperture appropriately sized to place around the catheter of a continent ostomy port. The body portion of the pad is sized and shaped for placement against a user's skin beneath a face plate of the ostomy port. The pad is formed of a soft, flexible material to thereby cushion and protect a user's skin from contact with the ostomy port face plate, wherein the pad body portion has a distal surface provided with a central indented region to thereby accommodate the distal portions of the continent ostomy port.

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IN THE DRAWINGS

Figures 28 through 35 have been added in keeping with the enclosed Letter to Drafting Division.

IN THE CLAIMS

Claim 1 - 37 have been cancelled.

Claims 38 through 69 have been added as new claims as set forth above.

FIG. 28